



2004D-0510

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Rm 1061  
Rockville, MD 20852

Re: Docket Number 2004D-0510

Attn: Tim Hansen  
Center for Food Safety and Applied Nutrition

Dear Mr. Hansen:

In reference to the proposed changes in the seafood inspection program for the certification of live and perishable products for export to the European Union we have the following comments;

1.- We are NOT in favor of NMFS or NOAA to certify live shipments.

The reasons behind our opinion are:

- A) There is a significant cost applied to the service these two agencies provide, making it even more expensive to export. The Federal Government is spending considerable sums of money promoting U.S. Agricultural products abroad, both through personnel and trade promotions in the EU. Adding significant and unnecessary additional cost of another layer of inspection via this proposal goes against what the Federal government is doing to motivate exports. Having worked in the past with both NMFS and FDA for exports to the EU and with the Washington department of Health for exports to Asia, I can tell you that our experience has been much more positive under the current arrangement with FDA.
- B) In the past we have used NMFS for export certificates and the process seemed ridiculous. An inspector needed to show up at the airport just to look at the packed product. Each inspection was being billed at a fairly high cost, including travel time for the inspector. The "inspection" consisted of looking at the boxes and that was it. If the inspector is not available for any reason, shipments are cancelled and need to be rescheduled. As you are aware many documents are required to be sent with international shipments that have precise dates, harvest

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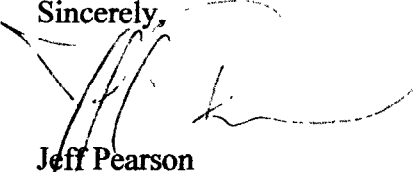
areas and volumes that match the actual date of shipment. Having delays or cancellations due to inspector being unavailable only leads much more cost to export live shellfish. Our Shellfish products are highly desired in many parts of the world but are limited if the cost becomes too high. Having an inefficient inspection system only adds to the limitation of export opportunity.

- C) NOAA and NMFS have no interaction whatsoever with the Sanitary and Shellfish Health Programs. Why is there a proposal to involve agencies that are not familiar with this?
- D) Our export program currently resides within FDA who certifies our HACCP Program and our Water Certification via the Washington Department of Health. It has worked smoothly and efficiently. FDA is familiar with the Shellfish Sanitation Program throughout the State.
- E) We have worked successfully with FDA to certify our shipments in the past two years. Why change what has worked perfectly?

In summary, the proposed changes will just make the process more bureaucratic, more costly and less efficient.

If you have any questions regarding our opinion, please do not hesitate to call me.

Sincerely,



Jeff Pearson  
President